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Honorable Judge James Donato San Francisco Courthouse, Courtroom 11, 19th Floor 450 Golden Gate Avenue, San Francisco, CA 94102

Re: Nektar Therapeutics v. Eli Lilly and Company, 23-cv-3943-JD (N.D. Cal.)

Dear Judge Donato,

Defendant Eli Lilly and Company seeks Plaintiff Nektar Therapeutics' supplemental production under Federal Rule of Civil Procedure 26(e) of newly available—but previously requested—materials about REZPEG's ongoing Phase 2b study in atopic dermatitis ("REZOLVE-AD trial"). Lilly served discovery requests for these documents nearly two years ago, long before the close of fact discovery. Nektar agreed to produce documents within its possession to Lilly, but certain data was blinded and unavailable to produce. That data about REZPEG is no longer blinded, and during Nektar's August 7, 2025 earnings call its CEO confirmed this new REZPEG data is relevant to the parties' claims and defenses and will "help" Nektar in the lawsuit. Yet Nektar refuses to produce this data without justification and in violation of its obligations under the Federal Rules.

I. BACKGROUND

Nektar's core litigation theory is that Lilly breached the Agreement in developing REZPEG's phase 2 precursor study to the REZOLVE-AD trial because its design was "unreasonable" and meant to "delay or thwart the development of REZPEG." Am. Compl. ¶¶ 58-60, 114. Nektar demanded that Lilly terminate the Agreement before the phase 2 atopic dermatitis study began, then moved forward with its own Phase 2b REZOLVE-AD trial for the same disease.

In November 2023, Lilly served RFPs seeking "[a]ll documents and communications relating to [Nektar's] Phase 2b study of REZPEG in atopic dermatitis"—the REZOLVE-AD study. See Lilly RFP No. 37; see also id. Nos. 8, 19, 24, 27-31, 33, and 35. In response, Nektar agreed to, and did, produce relevant documents that were available at the time. See Nektar's Obj. and Resp. to Lilly's RFP No. 37. But Nektar declined to produce documents related to "efficacy, tolerability, or safety data from the ongoing Phase 2 atopic dermatitis trial" because it was a "blinded" clinical trial at that point. 1/10/2025 K. Batter Email to A. Bailey. Lilly made clear on several occasions that Nektar must produce "all such data as soon as it becomes available, including after the close of fact discovery if necessary." 10/24/2024 A. Bailey Letter to Y. Kapgan (emphasis added); see also 12/23/2024 A. Bailey Email to K. Batter; 1/15/2025 P. Weeks Email to K. Batter. Aside from their unavailability, Nektar did not object to Lilly's requests for these Phase 2b REZOLVE-AD trial materials.

On June 24, 2025, Nektar held a public Investor Event to present a summary of new Phase 2b REZOLVE-AD trial data that confirmed the previously blinded information Lilly requested two years ago is now available. Lilly promptly asked Nektar to supplement its discovery responses and produce

specific materials falling under longstanding RFPs. *See* 7/3/2025 P. Weeks Letter to Y. Kapgan. After sitting on the request for nearly two weeks, Nektar ultimately offered to produce a self-selected list of documents that omits key information Lilly has sought since before the close of fact discovery, including Nektar's assessment of REZPEG's injection site reactions. 7/28/2025 D. Elihu Email. Ultimately, Lilly offered a final compromise on July 29—that Nektar produce only:

- Final, audited safety, efficacy, and biomarker data, including the Tables, Figures, and Listings for the data disclosed by Nektar for the REZOLVE-AD trial in June 2025 and presentations summarizing, analyzing, or evaluating REZOLVE-AD safety, efficacy, and biomarker data;
- Minutes or summaries of any meetings with KOLs regarding the REZOLVE-AD trial results;
- Minutes or summaries of Board meetings or Executive Committee Meetings, including the presentations or documents presented at these meetings related to the REZOLVE-AD trial;
- Injection site reaction data from the REZOLVE-AD trial;
- Documents describing Nektar's efforts to mitigate patients' injection site reactions and Nektar's efforts to conduct other ISR studies discussed by Nektar management during the Investor Event;
- Documents containing assessments of REZPEG's probability of success, development and commercialization timelines reflecting proposed timelines or start dates for Phase 3 or additional Phase 2 studies, and NPV calculations, following the publication of REZOLVE-AD data; and
- Email communications and Teams Chats related to the REZOLVE-AD study, including the topics above, from custodians Dr. Jonathan Zalevsky and Jennifer Ruddock from June 1, 2025 to present.

7/29/2025 P. Weeks Email. Nektar rejected this compromise. 7/30/2025 D. Elihu Email.

II. ARGUMENT

Despite previously agreeing to produce documents related to the REZOLVE-AD trial, Nektar rebuffed Lilly's request for supplementation, arguing: (1) the information is not relevant; and (2) the documents Lilly sought would "re-open discovery." 7/14/2025 M. McCauley Email. Both are wrong.

A. The REZOLVE-AD Trial Documents Are Relevant.

Nektar acknowledged during discovery that data and other documents related to REZPEG's successor Phase 2b atopic dermatitis trial—that Nektar alleges Lilly should have run—are relevant to this dispute. Nektar now contends for the first time that the 2025 REZOLVE-AD trial data is not relevant because "Nektar sued Lilly for breach of a contract that was in place only through mid-2023." *Id.* Nektar is wrong for several independent reasons.

First, Nektar's CEO recently said *Nektar intends to rely on this information at trial*. During Nektar's August 7 earnings call, he referred to the REZOLVE-AD "data that we reported" in June and said, "the results we have seen so far from REZPEG, I think, *will help us with the lawsuit*" because "the potential for this program is significant." Nektar Q2 2025 Earnings Call Tr. at 13 (emphasis added). Nektar intends to argue Lilly breached the Agreement because Nektar thinks REZPEG has "promise," and it intends to use the unblinded REZOLVE-AD data affirmatively. And on top of its Rule 26 duty to supplement, Nektar "must produce any document they intend to rely on, or else they are likely to be precluded from using the document at trial." *Pinson v. Prieto*, 2013 WL 12377237, at *3 (C.D. Cal. Mar. 12, 2013).

Second, Nektar alleges miscalculated Phase 1 efficacy data "hid REZPEG's true promise." Am. Compl. ¶ 3. But the Phase 2b data available now shows that REZPEG is *less efficacious* (61% improvement) than even the erroneously calculated data (showing 66% improvement) that Nektar contends "hid" REZPEG's promise. *Compare* 6/24/25 Nektar Press Release *with* 9/7/2022 EADV

Poster. This new Phase 2b data is more relevant and reliable than the prior data because, as Nektar's clinical expert explained,

A. Mostaghimi Dep. Tr. at 185:2-9. As such, the updated Phase 2b data refutes Nektar's allegations about the effect of the allegedly erroneous calculation on "the market, customers and consumers." Am. Compl. ¶ 93.

Third, Nektar's own experts confirm the data is highly relevant. Its clinical expert says REZPEG's is subject to new data from and he explicitly

Mostaghimi Rep. ¶¶ 113, 120-121. Its industry expert similarly said his estimates from the REZOLVE-AD trial. M. Robbins Rep. ¶ 241. Lilly is likewise entitled to review the data to determine how it should be used at trial.

Fourth, the parties dispute the impact of REZPEG's injection site reactions on its suitability as an atopic dermatitis treatment. Nektar's alleges "Lilly's purported concerns about ISRs were not commercially reasonable." Am. Compl. ¶ 54. But the sparse REZOLVE-AD trial data already disclosed shows REZPEG continues to create persistent, prevalent injection site reactions that Lilly predicted would be undesirable to patients. 6/24/2025 Nektar Press Release (reporting ISRs observed in 69.7% of all REZPEG-treated patients). And Nektar admitted during the Investor Event that it is now "[p]lanning ISR mitigation strategy." These revelations undermine a host of Nektar's litigation contentions, including that

Mostaghimi Rep. ¶ 14(d), and that REZPEG does not present an

J. Zalevsky Dep. Tr. at 296:9-18.

B. Nektar Has a Duty to Supplement under Rule 26(e).

"Federal Rule of Civil Procedure 26(e) imposes an ongoing duty to supplement all discovery responses 'in a timely manner if the party learns that in some material respect the disclosure or response is incomplete," which is true of the Phase 2b REZOLVE-AD trial data. Williams v. Woodford, 2010 WL 4530160, at *3 (E.D. Cal. Nov. 2, 2010). Nektar contends the relief Lilly seeks would "re-open discovery." 7/14/2025 M. McCauley Email. This is not true—Lilly asks only for documents responsive to RFPs served during fact discovery that are now available to Nektar; it does not seek to reopen fact or expert discovery or to move any case deadline, nor will the relief sought impact pending dispositive motions. And Nektar's duty to supplement under Rule 26(e) remains even after the close of fact discovery. See Gamevice, Inc. v. Nintendo Co., 2019 WL 5565942, at *2 (N.D. Cal. Oct. 29, 2019). Rule 26(e) "on its face, makes no distinction between information-including documents-acquired prior to and after the conclusion of fact discovery (or indeed of any discovery)." Pizza Pub. Co. v. Tricon Glob. Restaurants, Inc., 2000 WL 1457010, at *1 (S.D.N.Y. Sept. 29, 2000).

Nektar says it will not supplement unless Lilly agrees to produce more data for CD200R, one of the comparator drugs for REZPEG. 7/28/2025 D. Elihu Email. This new request has no bearing whatsoever on Nektar's obligation under the Federal Rules to supplement its discovery. Regardless, the Court has already ruled on extensive briefing about the proper scope of comparator drug discovery (see ECF No. 77; 3/27/2025 Hr'g Tr. at 4:12-24 ("THE COURT: Comparables are done.")).

* * *

Lilly respectfully requests the Court order Nektar (1) produce communications and documents responsive to Lilly's previously served RFPs, consistent with Lilly's July 29 compromise offer; and (2) supplement its written discovery responses to account for the Phase 2b REZOLVE-AD trial data.

Respectfully submitted,

Ryan J. Moorman

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